

TORGLIP R

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TORGLIP R (Remogliflozin Etabonate and Vildagliptin Tablets)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Vildagliptin: The administration of vildagliptin results in a rapid and complete inhibition of DPP-4 activity, resulting in increased fasting and postprandial endogenous levels of the incretin hormones GLP-1 (glucagon-like peptide 1) and GIP (glucose-dependent insulinotropic polypeptide). **Remogliflozin:** As an active ingredient, ZUCATOR contains Remogliflozin etabonate (RE). It is the prodrug of remogliflozin, an inhibitor of sodium-glucose co-transporter 2 (SGLT2), enabling urinary glucose excretion to reduce hyperglycemia for the treatment of type 2 diabetes.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substance (Remogliflozin Etabonate and Vildagliptin) or any of the excipients.

WARNINGS & PRECAUTIONS: if you are taking an anti-diabetic medicine known as a sulphonylurea, if you have moderate or severe kidney disease, if you are on dialysis, if you have liver disease, if you suffer from heart failure, if you have or have had a disease of the pancreas, If you have previously taken TORGLIP R but had to stop taking it because of liver disease, you should not take this medicine, Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking TORGLIP R Tablets. Should these occur, you should promptly consult your doctor TORGLIP R should not be initiated in patients with moderate to severe renal impairment due to its mechanism of action, Remogliflozin etabonate produces glycosuria and an osmotic diuresis, Consequently, there may be a decrease in intravascular volume that could result in hypotension, hem concentration, or electrolyte abnormalities., Rare cases of diabetic ketoacidosis (DKA), including life-threatening and fatal cases, have been reported in patients treated with sodium-glucose co-transporter 2 (SGLT2) inhibitors, Urinary tract infections were reported for remogliflozin up to 24 weeks. Urinary glucose excretion may be associated with an increased risk of urinary tract infection, In patients with diabetes mellitus receiving other SGLT2 inhibitors, reports of necrotizing fasciitis of the perineum (Fournier's Gangrene), a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in post marketing surveillance., Patients on oral contraceptives should be advised to use alternative, non-hormonal methods of birth control during treatment with remogliflozin etabonate.

DRUG INTERACTION: Thiazides or other diuretics, corticosteroids, thyroid medicines, certain medicines affecting the nervous system, As the effectiveness of oral contraceptives may be negatively impacted. Therefore, patients on oral contraceptives should be advised to use alternative, non-hormonal methods of birth control during treatment with remogliflozin etabonate, Concomitant administration of remogliflozin etabonate and bupropion does not affect the steady state PK of RE or bupropion and has no impact on urine glucose excretion,

There is a potential for CYP inducers to alter the pharmacokinetics of remogliflozin and its metabolites

ADVERSE REACTIONS: Trembling, headache, dizziness, nausea, low blood Glucose, Tiredness, weakness, low blood glucose, Constipation, Sore throat, runny nose, Weight increase, swollen hands, ankle or feet (oedema), swollen hands, ankle or feet (oedema), joint pain, low, fever, excessive sweating, chills, heartburn, Diarrhoea, flatulence, Itchy rash, inflammation of the pancreas, localised peeling of skin or blisters, muscle pain, Asthenia, Pyrexia, Bacteriuria, Urinary tract infection, Viral upper respiratory tract Infection, Glomerular filtration rate decreased, Dyslipidaemia, Hypoglycaemia, Ketonuria, Cough, Orthostatic hypotension, Anaemia, Eosinophilia, Iron deficiency anaemia, Microcytic anaemia, Thrombocytopenia, Thrombocytosis, Vertigo, Eye pain, Lacrimation increased Abdominal discomfort, Abdominal pain, Abdominal pain upper, Gastritis, Gastroesophageal reflux, Hyperchlorhydria, Stomatitis, Hyperbilirubinaemia, Gastroenteritis, Genital infection fungal, Herpes zoster, Lower respiratory tract, Periodontitis, Pharyngitis, Pulpitis dental, Pyuria, Upper respiratory tract, Vaginal infection, Viral infection, Vulvovaginal candidiasis, Vulvovaginitis, Blood bicarbonate abnormal, Blood cholesterol increased, Blood creatinine increased, Blood lactic acid increased, Blood pressure increased, Blood triglycerides increased, Electrocardiogram QT, Gamma-glutamyltransferase, Hepatic enzyme increased, Low density lipoprotein, Weight decreased, Decreased appetite, Diabetic ketoacidosis, Hypercholesterolemia, Hypertriglyceridaemia, Hypocalcaemia, Lactic acidosis, Polydipsia, Arthralgia Back pain, Costochondritis, Musculoskeletal pain, Myalgia Pain in extremity, Dizziness, Hypoaesthesia, Anxiety, Insomnia.

Manufactured by:

Glenmark Pharmaceuticals Ltd.

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(Additional information is available on request)